

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE
MEDICINE,

Plaintiff,

v.

IMSTEM BIOTECHNOLOGY, INC., XIAOFANG
WANG, and REN-HE XU,

Defendants.

C.A. NO. 1:17-cv-12239-ADB

**ASTELLAS' MEMORANDUM IN SUPPORT ITS MOTION FOR ENTRY OF
PROPOSED JUDGMENT AND FOR ADDITIONAL FINDINGS AND CONCLUSIONS
CONCERNING 93A**

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I. INTRODUCTION

On February 5, 2021, following a two and a half week trial, the Court issued a nearly 50 page decision resolving the factual disputes in the case. Consistent with Astellas' complaint, the Court found that Astellas scientists, Robert Lanza and Erin Kimbrel, were the original and true inventors of the breakthrough stem cell technology at issue, while Defendants Ren-He Xu and Xiaofang Wang made no inventive contributions. Rather, Drs. Xu and Wang, after monitoring Astellas as a competitor, submitted a patent application on Astellas' HB-MSC method "to prevent ACT[] from using their technology to go to clinic and develop [their] product" and to use as a bargaining chip in future litigation. Consequently, the Court held that Drs. Lanza and Kimbrel were the only true inventors of the '551 patent and that, contrary to Defendants' counterclaims, Drs. Xu and Wang had not contributed to the invention of Astellas' '956 and '321 patents. With respect to Astellas' claim under Chapter 93A, the Court found that the Defendants' actions were wrong, but their acts did not rise to the level of egregiousness required for a Chapter 93A violation.

Astellas proposes the attached final judgment, which gives effect to the Court's rulings. It removes Drs. Wang and Xu as inventors on the '551 patent and a second patent, U.S. Patent 10,557,122 ("the '122 patent"), that the parties agreed would be subject to the Court's decision, and transfers ownership of both patents to Astellas. This result is not disputed by Defendants.

In addition, the judgment effectuates the Court's findings by ordering Defendants to correct inventorship and transfer ownership to Astellas of PCT/US2013/048291 ("the '551 PCT"), the application from which the '551 patent issued, and to cooperate in correcting inventorship and transferring ownership of any remaining foreign patents or applications based on that application. These include an issued patent in China and pending applications in Hong Kong and Canada. Despite admitting that the '551 PCT application is identical to the '551 patent, Defendants contend that the Court's judgment did not "reach" the '551 PCT or other patents and applications stemming

from it. But that contention is contrary to Federal Circuit precedent, which authorizes correction of inventorship and transfer of PCT and foreign applications corresponding to a U.S. application whose inventorship has been determined by a Court. And it would make no sense for Defendants to continue to hold and control the foreign applications based on the very PCT application that gave rise to the '551 patent and which was central to the trial.

With respect to any remaining pending applications in the United States, Courts have held that Section 256 itself is not the mechanism for correcting inventorship, but parties may be ordered to correct and transfer ownership of pending applications under the Court's equitable power pursuant to a violation of a state law statute, such as Chapter 93A. While the Court did not find a violation of Chapter 93A based on Defendants' *pretrial* actions, their *post-trial* actions—refusing to return control of the '551 PCT application and other foreign patents and applications despite the Court's inventorship rulings—call out for the Court to modify its findings and conclusions solely for the purpose of equitably returning to Astellas its remaining intellectual property.

II. BACKGROUND

From the outset, this case, including Astellas' Chapter 93A claim, has been about Defendants improperly taking and claiming credit for Astellas' breakthrough inventions—the HB-MSC method, the resulting HB-MSCs, and their therapeutic uses. *See* Compl. ¶ 1 (Nov. 13, 2017) ECF No. 1 (“This action concerns a pioneering development in the creation of mesenchymal stem cells, useful in treating a number of disorders, in particular, immune disorders such as multiple sclerosis.”); Amend. Compl. ¶ 1 (Oct. 3, 2019) ECF No. 113 (same). Indeed, Defendants themselves have repeatedly stressed that this whole case is centered on inventorship. *See, e.g.*, Defs. Mot. to Amend Countercls. at 1-2, ECF No. 71 (“This is an inventorship dispute arising from the parties' once-amicable scientific collaboration in the development of protocols for making, and methods of using, mesenchymal stem cells (“MSCs”))” (repeated in ECF Nos. 109 at

1; 135 at 1; 183 at 2).

Now that the Court has determined the true inventors, Astellas' remedies are not limited to just the '551 and '122 patents. Part of Defendants' improper behavior, for which Astellas sought relief, was that Drs. Xu and Wang "filed the applications that led to the '551 patent" in which "Drs. Xu and Wang claim that they invented the method for making mesenchymal stem cells from embryonic stem cells using a hemangioblast intermediate—a method that was, in fact, invented by Drs. Kimbrel and Lanza during their employment by SCRMI and/or Astellas." Compl. ¶ 7, ECF No. 1; Amend. Compl. ¶ 7, ECF No. 113 (same). As Astellas explained in its original Complaint, these applications include the '551 PCT application. Compl. ¶ 47, ECF No. 1; Amend. Compl. ¶ 47, ECF No. 113 (same). Thus, Astellas requested an order transferring and/or granting a constructive trust for Astellas over the PCT application and any other applications deriving from Defendants' false claims of inventorship. Compl. ¶ 86(E), (F), ECF No. 1; Amend. Compl. ¶ 92(E), (F), ECF No. 113 (same).

As Defendants themselves explained to this Court, "the '551 PCT Application is substantively identical to the '551 Non-Provisional Application, and thus the '551 Patent. This is of necessity; an applicant for a patent may not add new subject matter to a PCT, or a national stage ('non-provisional') patent application after its filing date." Defs.' Trial Mem. With Proposed Findings of Fact & Conclusions of Law ("Defs.' Trial Mem."), ECF No. 221 at ¶ 62 n.9; *see also* [Corrected] Defs.' Post-Trial Proposed Findings of Fact & Conclusions of Law ("Corr. Defs.' Prop. FOF/COL"), ECF No. 247-1 at ¶ 134 (explaining that "[t]he '551 PCT Application was the basis for the '551 national stage and thus has the same specification and figures as the '551 patent"). Moreover, Defendants expressly recognized in their pretrial memorandum that Astellas "contend[s] that Wang and Xu claimed Plaintiff's (alleged) technology as their own by seeking

patent protection for a method for producing human embryonic stem cell-derived mesenchymal stem cells from a hemangioblast intermediary in the '551 PCT Application." Defendants' Trial Mem., ECF No. 221 at ¶ 138. As the '551 PCT Application "is substantively identical to" the '551 patent (Defendants' Trial Mem., ECF No. 221 at ¶ 62 n.9), containing "the same specification and figures as the '551 patent" (Corr. Defendants' Prop. FOF/COL, ECF No. 247-1 at ¶ 134), the Court's decision as to inventorship on the '551 patent controls the inventorship of the '551 PCT Application and any foreign applications derived from it.

III. THE COURT SHOULD ENTER ASTELLAS' PROPOSED FINAL JUDGMENT AND MAKE ADDITIONAL FINDINGS OF FACT AND/OR CONCLUSIONS OF LAW AS NEEDED

The Court has not yet entered a final judgment in this case. Given the parties' dispute about the appropriate form of judgment and remedy for its conduct, Astellas attaches a proposed final judgment as Exhibit A. Notwithstanding Defendants' contention that the Court's findings "did not reach" anything beyond the '551 and '122 patents, the Court's power is not so limited.

A. There Is No Dispute As To The Judgment Of Inventorship And Ownership Of The '551 And '122 Patents

Based on the Court's findings and conclusions after trial, and meet and confers between the parties, there appears to be no dispute that the Court can and should enter judgment ordering the Director of the U.S. Patent & Trademark Office ("Patent Office") to add Drs. Kimbrel and Lanza and remove Drs. Xu and Wang as inventors on the '551 and '122 patents, and ordering Defendants to cooperate with Astellas to effectuate the change in inventorship and, since ownership flows from inventorship, in ownership of the '551 and '122 patents. *See* ECF No. 255 at 47; 35 U.S.C. § 256(b) (courts resolving inventorship actions "may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly"); *Regents of Univ. of New Mexico v. Knight*, 321 F.3d 1111, 1118-119 (Fed. Cir.

2003) (“ownership of a patent vests in the inventor by operation of law”).

B. Final Judgment Should Include Transfer Of Inventorship And Ownership Of The ’551 PCT Application And Foreign Applications Or Patents Based On It

The Court should also order correction and transfer of ownership of the ’551 PCT application (*i.e.*, the application that was the basis for the ’551 patent) along with any foreign applications or patents based on it.

The Federal Circuit has held that, having determined inventorship of the underlying U.S. patent, the Court can “instruct [Defendants] to take appropriate action to change the inventorship designation on the foreign patent applications,” as “inventorship on such applications normally follows the inventorship designation in the originating country.” *Chou v. Univ. of Chicago*, 254 F.3d 1347, 1360 (Fed. Cir. 2001); *see also Admin. of the Tulane Educ. Found. v. Ipsen Pharma, S.A.S.*, 771 F. Supp. 2d 32, 37 (D.D.C. 2011) (denying motion to dismiss correction of inventorship claims that include “international (PCT) patent applications filed as counterparts to issued patents” because “Plaintiffs can, however, seek correction of inventorship for pending foreign applications”). Further, “it is well established that courts have authority to compel parties properly before them to transfer ownership of foreign patents, just as they would any other equitable remedy.” *SiOnyx LLC v. Hamamatsu Photonics K.K.*, 981 F.3d 1339, 1354 (Fed. Cir. 2020) (holding ownership of foreign patent applications should have been transferred where, in part, the U.S. patents for which the district court had ordered transfer of ownership claimed priority to the foreign patent applications such that those “applications must be for the same inventions as the Disputed U.S. Patents”).

Here, inventorship on the ’551 PCT application (and any foreign applications pending from it) follows the inventorship designation on the ’551 and ’122 patents. Defendants admit that the ’551 PCT application is substantively identical to the ’551 patent, and that it formed the basis for

that patent. Defendants' Trial Mem., ECF No. 221 at ¶ 62 n.9; *see also* Corr. Defendants' Prop. FOF/COL, ECF No. 247-1 at ¶ 134. Defendants' patent law expert, Dr. Zerhusen, testified extensively about the similarities between the '551 PCT application and the issued '551 patent, and Defendants' Counsel returned to the theme during closing, noting how the '551 PCT application included the elements, like IL-6, found in Astellas' patents, but claiming they were invented by Defendants. This evidence refutes any suggestion that the Court's judgment cannot reach the '551 PCT application.

What's more, inventorship of the subject matter in the '551 PCT application has been litigated throughout this case. Astellas explicitly stated in its original Complaint that Drs. Xu and Wang claimed that they invented Astellas' HB-MSC technology in the '551 PCT application that led to the '551 patent. Compl. ¶¶ 7, 47 ECF No. 1; Amend. Compl. ¶¶ 7, 47, ECF No. 113. Astellas sought transfer of title of and a constructive trust over all patent applications, patents, and other materials that wrongfully contained Astellas' intellectual property since the beginning as well. Compl. ¶ 86(E), (F), ECF No. 1 (emphasis added); Amend. Compl. ¶ 92(E), (F), ECF No. 113 (same). Defendants have thus been on notice for years that Astellas was seeking through this suit to reclaim all HB-MSC-related intellectual property invented by Drs. Kimbrel and Lanza that Defendants wrongfully claimed as their own.

Defendants further argue, with respect to the Chinese patent derived from the '551 patent, that they no longer have control over that application and patent, as they assigned it to Zhuhai Hengqin ImStem Biotechnology Co., Ltd. ("Zhuhai ImStem"). This argument is disingenuous at best and, once again, shows how Defendants are still trying to extract bargaining chips from Astellas by wrongfully keeping intellectual property filed on Astellas' HB-MSC technology to which Defendants never should have had any rights to in the first instance. This Court has power

over the named Defendants, Xiaofang Wang, Ren-He Xu, and the U.S. ImStem company. As Defendants admitted in sworn interrogatory responses, Dr. Wang and Michael Men both work for both U.S. and Zhuhai ImStem, with Dr. Men being the Acting Chief Executive Officer of U.S. ImStem and the Chief Executive Officer of Zhuhai ImStem. TX-MJ at 12. Dr. Xu further admitted he was a shareholder, directly or indirectly, in both the U.S. and Zhuhai ImStem companies and that he appears sometimes on behalf of Zhuhai ImStem. Tr. 10-132:3-133:20. Further, documents indicate that Dr. Xu holds the position of “Supervisor” at Zhuhai ImStem. TX-LA at AIRM00299758 (under “Main personnel information”). The Court can thus order those parties that it indisputably has power over—Drs. Wang, Xu, and ImStem—to cooperate with Astellas to transfer inventorship and ownership over the Chinese patent application (now patent) to Astellas. Defendants should not be permitted to effectively keep stolen goods via a corporate shell game.

The Court should thus enter judgment ordering Defendants to cooperate with Astellas to correct inventorship and to transfer ownership of the ’551 PCT application and to further assist in transferring any foreign applications based on the ’551 PCT application to Astellas.

C. Defendants Should Correct Inventorship And Transfer Any Pending U.S. Applications Based On The Applications Leading To The ’551 Patent

Finally, Defendants should assist in changing inventorship and transfer any applications in the U.S. that are based on the ’551 PCT application, leading to the ’551 patent. Currently, Defendants have one such pending application, No. 16/745,944 (the ’944 application), filed on January 17, 2020.¹ Consistent with Defendants’ expert’s testimony at trial about PCT applications,

¹ This filings in this application, publicly available government records, are available by searching the Patent Office’s Public PAIR database, available at <https://portal.uspto.gov/pair/PublicPair>. As such, this Court may take judicial notice of the application and its filings. *See, e.g., Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1306 (Fed. Cir. 2005) (district court permissibly took judicial notice of patent’s reinstatement, which was evident from Patent Office filings that occurred after close of the evidence, under Fed. R. Evid. 201(f)).

the disclosure of the '944 application is identical to the '551 patent. The current pending claims recite methods for (1) producing embryoid bodies or (2) hemangioblasts from hESCs cultured under serum- and feeder-free conditions by using a GSK3 inhibitor, specifically BIO, at a concentration ranging from 0.05 μ M to 0.2 μ M. *See* Applicant Response to Notice to File Missing Parts of Application & Preliminary Amendment at 5-6, U.S. Patent App. No. 16/745,944 (filed Sept. 4, 2020). Yet, despite these claims reciting only things this Court found either invented or known by Drs. Kimbrel and Lanza at trial, Defendants have not yet informed the Patent Office about this *litigation*, let alone this Court's decision. In essence, despite fully litigating the precise issues in these pending claims with respect to inventorship—and losing—Defendants now want to act like this Court's decision never occurred and continue to seek patents on technology this Court determined after a more than two week trial was invented by Astellas.

To the extent Defendants' argument is that this Court lacks equitable powers to compel them to transfer ownership of this application (or any others pending but not yet publicly available) because the Court denied Astellas' Chapter 93A claim, Astellas respectfully requests that the Court reconsider its conclusions of law as to Astellas' Chapter 93A claim based on Defendants' post-trial activity—namely, refusing to return the related applications, despite the inventorship findings of this Court—and order the equitable relief of returning the HB-MSC intellectual property Defendants improperly took and now seek to retain. Defendants' alternative would be for Astellas to engage in a never ending game of “whack-a-mole,” filing new lawsuits as Defendants file patent application after patent application on subject matter this Court has already determined they did not invent.

Thus, Astellas respectfully requests that the Court reconsider its conclusions of law as to Astellas' Chapter 93A claim (pursuant to Federal Rules of Civil Procedure 52(b) and/or 59(a)(2))

and order the equitable relief of returning the HB-MSC intellectual property Defendants improperly took and now seek to retain. *See Governo Law Firm LLC v. Bergeron, et al.*, No. SJC-12948, 2021 Mass. LEXIS 207, *13-14 (Apr. 9, 2021) (holding trial court abused its discretion by not including certain materials in the scope of an injunction where “the judge allowed the defendants to continue to use [the materials] and thereby improperly permitted them to continue to benefit from their theft”).

IV. CONCLUSION

For the above reasons, Astellas respectfully requests that the Court enter Astellas’ proposed judgment, attached to its Motion as Exhibit A.

Dated: April 21, 2021

Respectfully submitted,

/s/ David P. Frazier

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CERTIFICATE OF SERVICE

I hereby certify that this document, which was filed with the Court through the CM/ECF system, will be sent electronically to all registered participants as identified on the Notice of Electronic Filing, and paper copies will be sent on April 21, 2021 to those identified as non-registered participants.

/s/ David P. Frazier _____

David P. Frazier